DP BARCODE No.: D351079; **REG. No.:** 70506-140; **PRODUCT NAME:** Asulam Sodium Technical

DATE: 19 / MAY / 2008

SUBJECT: **FEE.PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP [ ]**
DP BARCODE No.: D351079 **REG. No.:** 70506-140
PRODUCT NAME: Asulam Sodium Technical
COMPANY: United Phosphorous Incorporation (UPI)
PCC: 106902; **Decision No.:** 391429; **ACTION CODE:** R340
FOOD USE [X]
INTEGRATED FORMULATION: Yes [X] No [ ]

FROM: Shyam B. Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Tracy White / Joanne Miller, RM 23
Herbicide Branch / RD (7505P)

INTRODUCTION

The registrant has submitted an application to amend the registration of the asulam sodium technical produced at an alternate production site in India. The amendment reflects the production of the TGAI/MUP by UP Ltd, Mumbai, India. In support of this amendment, the registrant has submitted an alternate formulation CSF (dated 03-13-08) supported by five batch analysis under MRID No. 473812-01. The basic formulation CSF (dated 10-18-96) indicated the production site for the TGAI/MUP in England by previous owner Rhone Poulenc Ag Company with Reg. No. 264-505. The nominal concentration of the active ingredient, asulam sodium technical in the basic CSF is 88.6% which is also the product label claim nominal concentration (accepted product label dated 10-01-2002). TRB has been asked to evaluate the CSF for alternate formulation and the supporting product chemistry data and determine their acceptability.

SUMMARY OF FINDINGS

1. The nominal concentration of the active ingredient asulam sodium in the alternate formulation is 89.6% which falls within the certified limits of the label claim nominal concentration of 88.6%. The average concentration of the active ingredient was found to be 89.6% as determined by the five batch analysis of the batches from the alternate site in India.

2. The alternate formulation CSF (dated 03-13-08) is filled out correctly and completely. The nominal concentration of the active ingredient (89.6%) falls within the certified limits of the product label claim nominal concentration (88.6%). The alternate CSF is in compliance with PR Notice 91-2 and 40CFR§152.43. The impurity profile of the accepted basic CSF (dated 10-18-96) and the proposed alternate CSF (dated 03-13-08) is very similar. Both the CSF's contain identical impurities which differ slightly in their concentration levels. The concentrations of all the impurities in alternate CSF (03-13-08) are less than or equal to the concentrations of respective impurities in basic CSF (dated 10-18-96). The physical-chemical characteristics mentioned on the CSF's are very similar.

3. The product chemistry data submitted corresponding to guideline 830.1700 (preliminary analysis) supported the proposed alternate CSF (dated 03-13-08). The five batches of asulam sodium TGAI/MUP, produced at new site in India were analyzed to determine the active ingredient and the associated impurity contents in the technical. The analysis was performed using validated methods of HPLC-UV. The external standard quantification method was used to quantify the levels of asulam sodium and associated impurities. The identity of asulam sodium and its associated impurities were confirmed by HPLC and LC-MS based on elution pattern, retention time and mass. The analytical methods were validated for precision, linearity, accuracy, LOD, and LOQ under the experimental parameters [MRID No. 473812-01].

CONCLUSIONS

TRB has evaluated the product chemistry data submitted to support the alternate formulation CSF (dated 03-13-08) for asulam sodium technical and has determined that:

1. The data submitted for the guideline 830.1700 (preliminary analysis) is acceptable.

2. The data submitted for five batch analysis supports the proposed alternate formulation CSF (dated 03-13-08). The proposed alternate formulation CSF is substantially similar to the accepted CSF for basic formulation (dated 10-18-96) in chemical composition and physical-chemical characteristics. The proposed alternate CSF (dated 03-13-08) is acceptable.

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830.1550. Product Identity & composition: (MRID No. 473812-01)

Common Name: Asulam Sodium
Chemical Name: Methyl [(4-aminophenyl)sulfonyl]carbamate sodium salt
CAS No.: 2302-17-2
Molecular weight: 252.20

Asulam

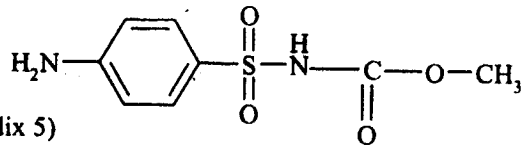
methyl [(4-aminophenyl)sulfonyl)]carbamate

230.24

$C_8H_{10}O_4N_2S$

[3337-71-1]

97.4% (Refer Appendix 5)



Pages 4-13 Manufacturing process information may be entitled to confidential treatment

Pages 14-15 Confidential Statement of Formula may be entitled to confidential treatment